EMA/51634/2016
EMEA/H/C/002155

EPAR summary for the public

Tobi Podhaler

tobramycin

This is a summary of the European public assessment report (EPAR) for Tobi Podhaler. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Tobi Podhaler.

What is Tobi Podhaler?

Tobi Podhaler is a medicine that contains the active substance tobramycin. It is available as capsules (28 mg) containing a dry powder for inhalation using a portable inhaler device.

What is Tobi Podhaler used for?

Tobi Podhaler is used to suppress chronic lung infection caused by bacteria called *Pseudomonas aeruginosa* in adults and children aged 6 years and over who have cystic fibrosis. Cystic fibrosis is an inherited disease in which there is accumulation of thick mucus in the lungs that allows bacteria to grow more easily causing infections. *P. aeruginosa* is a frequent cause of infections in cystic fibrosis patients.

Because the number of patients with cystic fibrosis and *P. aeruginosa* bacterial lung infection is low, the disease is considered 'rare' and Tobi Podhaler was designated an 'orphan medicine' (a medicine used in rare diseases) on 17 March 2003.

The medicine can only be obtained with a prescription.

How is Tobi Podhaler used?

Tobi Podhaler is inhaled using a hand-held device called Podhaler. The capsules are only to be inserted into the Podhaler and must never be swallowed. The recommended dose is four capsules twice a day (as close as possible to 12 hour intervals) for four weeks, followed by four weeks without treatment. The patient should continue with a cycle of four weeks 'on' treatment followed by four weeks 'off'

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

treatment for as long as the doctor believes the patient is benefiting from it. If the patient's lung infection gets worse, the doctor should consider replacing or adding another treatment to Tobi Podhaler. For more information on how to use Tobi Podhaler, see the instructions in the package leaflet.

How does Tobi Podhaler work?

The active substance in Tobi Podhaler, tobramycin, is an antibiotic that belongs to the group 'aminoglycosides'. It works by disrupting the production of proteins that *P. aeruginosa* needs to build its cell walls. This damages the bacteria and eventually kills them.

Tobramycin is a well-known antibiotic that has been used to treat lung infection in cystic fibrosis patients, available in the form of a solution used with a nebuliser (a machine that changes a solution into an aerosol that the patient can breathe in). Tobi Podhaler is intended to increase the convenience of taking tobramycin for patients.

How has Tobi Podhaler been studied?

The applicant presented data on an existing nebuliser solution containing tobramycin called Tobi. They also presented data from the published literature.

Tobi Podhaler was studied in two main trials in patients who had cystic fibrosis with *P. aeruginosa* lung infection. The first trial, which involved 102 patients aged 6 to 21 years, compared Tobi Podhaler with placebo (a dummy treatment), while the second, involving 553 mostly adult patients, compared it with Tobi. The trials lasted 24 weeks (three treatment cycles). The main measure of effectiveness was the change in FEV_1 at the end of the treatment period of cycle 1 in the first study and at the end of the treatment period of cycle 3 in the second study. FEV_1 is the most air a person can breathe out in one second.

What benefit has Tobi Podhaler shown during the studies?

Tobi Podhaler was more effective than placebo in treating *P. aeruginosa* infection in patients with cystic fibrosis. After four weeks of treatment, the patients taking Tobi Podhaler had an improvement in FEV_1 of 13.2%, while patients taking placebo had a reduction in FEV_1 of around 0.6%. When the patients in the placebo group were switched to Tobi Podhaler for the second and third cycles they also experienced a similar improvement in FEV_1. The effect of Tobi Podhaler was similar to that of Tobi after three cycles of treatment.

What is the risk associated with Tobi Podhaler?

The most common side effects with Tobi Podhaler (seen in more than 1 patient in 10) are haemoptysis (coughing up blood), dyspnoea (difficulty breathing), dysphonia (hoarseness), cough and productive cough (producing mucus), oropharyngeal pain (affecting the mouth and throat) and pyrexia (fever). For the full list of all side effects reported with Tobi Podhaler, see the package leaflet.

Tobi Podhaler must not be used in people who are hypersensitive (allergic) to tobramycin, any aminoglycoside or any of the other ingredients.

Why has Tobi Podhaler been approved?

The CHMP decided that Tobi Podhaler's benefits are greater than its risks, since it is effective at treating lung infection in cystic fibrosis patients and given its added convenience for patients. The Committee therefore recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Tobi Podhaler?

A risk management plan has been developed to ensure that Tobi Podhaler is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Tobi Podhaler, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Tobi Podhaler

The European Commission granted a marketing authorisation valid throughout the European Union for Tobi Podhaler on 20 July 2011.

The full EPAR for Tobi Podhaler can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Tobi Podhaler, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Tobi Podhaler can be found on the Agency's website ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 02-2016.